In the Claims

Claims 1-28 (Canceled)

29. (New) A device suitable for topical delivery of a therapeutically effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium, said device coated with or incorporated with a polymer film or foam composition comprising said therapeutically effective agent.

30. (New) The device of claim 29 wherein the device is a tampon, tampon-like device, ring, sponge, pessary, suppository, pillow, pad, strip, cylinder, sphere or bead.

31. (New) The device of claim 30 wherein said composition delivers said therapeutically effective agent to said vaginal, nasal, buccal, labial or scrotal epithelium for a topical treatment or through said vaginal, nasal, buccal, labial or scrotal epithelium into a systemic circulation.

32. (New) The device of claim 31 wherein said device is the tampon-like device or tampon and wherein said composition is coated on said tampon-like device or tampon for administration of said therapeutically effective agent to the vaginal epithelium.

33. (New) The device of claim 32 wherein said composition comprises at least one substrate polymer or a mixture of substrate polymers and a therapeutically effective agent.

34. (New) The device of claim 33 wherein said substrate polymer is a hydrophilic or hydrophobic polymer or a mixture of both.

35. (New) The device of claim 34 wherein said substrate polymer is selected for the group consisting of polyethylene oxide, hydropropyl methylcellulose, gelatin, alginic acid, alginic acid sodium salt, polyethylene glycol, pectin, collagen, poloxamer, carbopol, microcrystalline cellulose, polyacrylic acid, polyethylene glycol, polypropylene glycol, divinyl glycol, polypropylene oxide, carboxymethyl cellulose, hydroxyethyl cellulose, polylactide, polyglycolide, polymethacrylic acid, poly-γ-benzyl-L-glutamate, polypropylene fumarate, poly-ϵ-caprolactone, poly-butylene terephthalate, polyvinyl alcohol, polyvinyl ether, poly-1-vinyl-2-pyrrolidinone, 2,5-dimethyl-1,5-hexadiene, divinyl benzene, polystyrene-divinyl benzene, poly-bis(*p*-carboxy-phenoxypropane)-*co*-sebacic acid, poly-β-hydroxybutyrate, poly-β-butyrolactone, tetraethylorthosilicate and

dimethyldiethoxysilane, each alone or in admixture.

36. (New) The device of claim 35 wherein said polymer is polyethylene oxide, hydropropyl methylcellulose, gelatin, alginic acid, alginic acid sodium salt, polyethylene glycol, pectin, collagen, poloxamer, carbopol or microcrystalline cellulose, each alone or in admixture.

37. (New) The device of claim 36 wherein said therapeutically effective agent is selected from the group consisting of a non-steroidal anti-inflammatory agent, anti-osteoporosis agent, calcium channel antagonist agent, local anesthetic agent, potassium channel antagonist agent, β-adrenergic agonist agent, vasodilatory agent, cyclooxygenase inhibitor agent, anti-fungal agent, antiviral agent, antimicrobial agent, antiparasitic agent, anti-epileptic agent, anti-migraine agent, anti-HIV agent, anti-neurodegenerative agent, anti-psychotic agent, chemotherapeutic agent, anti-neoplastic agent and opioid analgesic agent.

38. (New) The device of claim 37 wherein said nonsteroidal anti-inflammatory agent is selected from the group consisting of ketorolac, aspirin, ibuprofen, indometacin, phenylbutazone, bromfenac, fenamate, sulindac, nabumetone and naproxen;

wherein said calcium channel antagonist agent is selected from the group consisting of diltiazem, israpidine, nimodipine, felodipine, verapamil, nifedipine, nicardipine and bepridil;

wherein said potassium channel blocker agent is selected from the group consisting of dofetilide, almokalant, sematilide ambasilide, azimilide, tedisamil, sotalol, piroxicam and ibutilide;

wherein said β-adrenergic agonist agent is selected from the group consisting of terbutaline, salbutamol, metaproterenol, ritodrine;

wherein said COX-2 or COX-1 inhibitor agent is selected from the group consisting of naproxen, ketoprofen, ketorolac, indomethacin, diclofenac, teroxicam, celecoxib, meloxicam and flosulide;

wherein said vasodilator agent is selected from the group consisting of nitroglycerin, isosorbide dinitrate, and isosorbide mononitrate;

wherein said bisphosphonate agent is selected from the group consisting of alendronate, clodronate, etidronate, pamidronate, tiludronate, ibandronate, zoledronate, alpadronate, residronate and neridronate;

wherein said antifungal agent is selected from the group consisting of miconazole, terconazole, isoconazole, fenticonazole, tioconazole, fluconazole, nystatin, ketoconazole, clotrimazole, butoconazole, econazole, metronidazole and itraconazole;

wherein said antibacterial agent is selected from the group consisting of metronidazole, clindamycin, tetramycin, erythromycin, doxicycline, lumefloxacin, norfloxacin, afloxam, ciproflaxin, azitromycin, cefltoxime and doxicycline;

wherein said parasiticidal agent is metronidazole or clotrimazole;

wherein said antiviral agent is acyclovir or AZT;

wherein said anti-migraine agent is selected from the group consisting of almotriptan, eletriptan, flovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, ergotamine, dihydroergotamine, bosentan and lanepitant;

wherein said anti-cancer agent is selected from the group consisting of vincristine, cisplastin, doxorubicin, daunorubicin, etoposide, topotecan, irinotecan, paclitaxel, docetaxel, cyclophosphamide, methotrexate and gemcitabine;

wherein said anti-HIV agent is selected from the group consisting of saquinavir, ritonavir, indinavir, amprenavir, nelfinavir, lopinavir and ganciclovir; and

wherein said biotechnology-derived protein or peptide agent is selected from the group consisting of insulin, calcitonin, vasopressin, luprolide, somatostatin, oxytocin, bivalirudin, integrilin, natrecor, abarelix, gastrine G17, peptide, ziconotide, cereport, interleukin, humanized antibodies and growth hormone.

39. (New) The device of claim 38 wherein said composition further comprises a penetration enhancer, sorption promoter, mucoadhesive agent, hydrophilic or hydropholic release modifier, each alone or in admixture.

40. (New) The device of claim 39,

wherein said penetration enhancer is selected from the group consisting of sodium caproate, sodium caprylate, sodium caprate, sodium laurate, sodium myristate, sodium palmitate, sodium palmitoleate, sodium oleate, sodium ricinoleate, sodium linoleate, sodium stearate, sodium lauryl sulfate, sodium tetradecyl sulfate, sodium laryl sarcosine, sodium dioctyl sulfosuccinate, sodium cholate, sodium taurocholate, sodium glycocholate, sodium deoxycholate, sodium taurodeoxycholate, sodium glycodeoxycholate, sodium ursodeoxycholate, sodium chenodeoxycholate, sodium taurochenodeoxycholate, sodium glycol chenodeoxycholate, sodium cholylsarcosine, sodium *N*-methyl taurocholate, sodium tauro-24,25-dihydrofusidate, disodium polyoxyethylene-10 oleyl ether phosphate, esterification product of fatty alcohols, fatty alcohol ethoxylate with phosphoric acid or anhydride, ether carboxylate, succinylated monoglyceride, sodium stearyl fumarate, stearyl propylene glycol hydrogen succinate, mono/diacetylated tartaric acid ester of mono- and diglycerides, citric acid

esters of mono- and diglycerides, glyceryl-lacto esters of fatty acids, lactylic ester of fatty acids, alginate salt, ethoxylated alkyl sulfate, alkyl benzene sulfone, α-olefin sulfonate, acyl isethionate, acyl taurate, alkyl glyceryl ether sulfonate, octyl sulfosuccinate disodium, disodium undecylenamideo-MEA-sulfosuccinate, phosphatidic acid, phosphatidyl glycerol, polyacrylic acid, hyaluronate sodium, glycyrrhetinic acid, ethylene diamine tetraacetate, sodium citrate, chitosan, trimethyl chitosan, poly-*L*-arginine chitosan, poly-*L*-lysine chitosan, aminated gelatin, hexadecyl triammonium chloride, decyl trimethylammonium chloride, cetyl trimethylammonium chloride, alkyl benzyldimethylammonium chloride, diisobutyl phenoxyethoxydimethyl benzylammonium chloride, ethyl pyridinium chloride, isopropyl pyridinium chloride, *N*-lauryl,N,N-dimethylglycine, *N*-capryl,N,N-diethylglycine, polyoxyethylene coconut amine, poly-*L*-lysine, poly-*L*-arginine, lecithin, lysolecithin, hydroxylated lecithin, lysophosphatidylcholine, phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, didecanoyl-L-α-phosphatidylcholine, lauroylcarnitine, acylcarnitine, palmitoyl-D,L-carnitine, polyoxyethylene lauryl ether, polyoxyethylene monooleyl ether, ethoxydiglycol, polyoxyethylene nonylphenol polyoxyethylene octylphenol ether, polyoxyethylene cholesterol ether, polyoxyethylene soya sterol ether, α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, dimethyl-β-cyclodextrin, methylated-β-cyclodextrin, 2-hydroxypropyl-β-cyclodextrin, sorbitol, polyoxyethylene glycol ester, polyoxyethylene glycerol fatty acid ester, polyoxyethylene glycerol fatty acid ester, polyoxyethylene glyceride, polyoxyethylene vegetable or hydrogenated oil, polyoxyethylene monooleate, polyoxyethylene dilaurate, polyoxyethylene mono and dioleate, polyoxyethylene glyceryl laurate, polyoxyethylene glyceryl oleate, propylene glycol oleate, propylene glycol stearate, polyoxyethylene sorbitan monooleate, polyoxyethylene tristearate, polyoxyethylene hydrogenated castor oil, polyoxyethylene almond oil, polyoxyethylene apricot kernel oil, polyoxyethylene caprylic glyceride, polyoxyethylene capric glyceride, lauroyl macrogol glyceride;

wherein said mucoadhesive agent is selected from the group consisting of hydroxypropyl methylcellulose, carboxymethylcellulose, polylactide-coglycolide, chitosan, chitosan ester, trimethylene chloride chitosan, sodium alginate, poloxamer, pectin, polyacrylic acid, hyaluronic acid, polyvinyl alcohol, polyvinyl pyrrolidone, polycarbophil and carbopol; and

wherein said release modifier is selected from the group consisting of polyethylene glycol 200, polyethylene glycol 8000, poloxamer, polyoxyethylene glycerylcocoate, carbopol, suppocire AS2X, suppocire CM, Witepsol H15, Witepsol W25, mineral oil, corn oil, paraffin oil, canola oil, castor oil, cottonseed oil, lecithin, peanut oil, sesame oil, soybean oil and hydrogenated vegetable oil.

41. (New) The device of claim 40 wherein said penetration enhancer is present in amount from about 0.1% to about 60%, by weight, wherein said mucoadhesive agent is present in from about

0.5% to about 10%, by weight, and wherein said release modifier is present in amount from about to about 5% to about 70%, by weight.

42. (New) The device of claim 41 further comprising a therapeutically acceptable additive or excipient.

43. (New) The device of claim 42 wherein said additive or excipient is a solubilizing agent, buffering agent, filler, preservative, plasticizer, surfactant or anti-oxidant.

44. (New) The device of claim 43 wherein said composition is the film.

45. (New) The device of claim 44 wherein said film composition coating is wrapped around said tampon-like device or tampon.

46. (New) The composition of claim 45 wherein said film is composed of a single sheet or multiple sheets.

RESPONSE TO THE RESTRICTION/ELECTION REQUIREMENT

This Amendment is filed in response to the restriction requirement dated December 21, 2006.

Status of the Claims

Claims 1-28 previously pending in this application and were the subject of the restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1-19, drawn to a polymer foam or film composition for delivery therapeutically effective agents topically to nasal, buccal, vaginal, labial or scrotal epithelium or through nasal, buccal, vaginal, labial or scrotal epithelium into a systemic circulation, said composition comprising at least one substrate polymer or a mixture of substrate polymers a therapeutically effective agent, classified in class 424, subclasses 431, 434, and 435. If this Group is elected, then the below summarized Species Election is also required.

Group II: Claims 20 and 21, drawn to a device comprising a polymer or film composition of claims 1-18, said device suitable for delivery of therapeutically effective agents topically to a nasal, buccal, vaginal or labial cavity wherein said device is either coated with composition or said composition is incorporated into device, classified in class 514, subclasses 947, and 953+. If this Group elected, the below summarized Species Election is also required.

Group III: Claims 22-28, drawn to a method for topical or systemic delivery of drugs to or through nasal, buccal, vaginal, labial or scrotal epithelium, classified in class 424, subclass 430+. If this Group is elected, then the below summarized Species Election is also required.

Examiner argues that inventions I-III are related as product, apparatus, and process for use as the apparatus invention II and the process (invention III) claimed can be used to practice the product (invention I).

Inventions I and II can be shown to be distinct if either or both of the following can be shown: (1) the apparatus/device for using the product as claimed can be practiced with another materially different product or the product as claimed can used in a materially different apparatus/device of using that product. See MPEP 806.05(h). In the instant case, the apparatus for using the product as claimed can used with a materially different product, for example, a food product.

Inventions I and III can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process or apparatus using that product. See MPEP 806.5(h). In the instant case, the process of using the product as claimed can practiced with another materially different product. For example, invention III can be used an intravenous non-polymer containing drug formulation systemically.

Inventions II and III can be shown to be distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, ie., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP 806.5(h). In the instant case, the inventions as claimed are distinct because the inventions are either not capable of use together or can have a materially different design, mode of operation, function in view of their divergent subject matter. Specifically, Invention II is directed towards a device comprising a polymer foam or composition suitable for delivery of therapeutically effective agents topically, while invention III can be used to deliver intravenous non-polymer containing formulations systemically.

Because inventions I-III are independent or distinct for the reasons given coupled with the fact that a search is required for each group, restriction for examination purposes is proper. While Groups 1-11 can be identically classified under U.S. Classification guidelines, to search them together would present an undue search burden on the Examiner due to the extensive databases of patent and non-patent literature that would have to be searched in view of the divergent subject matter encompassed by the different groups. Thus, Groups I-III have been appropriately restricted on the basis being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Applicants disagree with Examiner's reasoning, at least insofar as Group I and II are concerned, however, to be responsive, Applicants elect, with traverse, to prosecute Group II, directed to the device. The traverse is based on reasoning that if the device of the invention comprises a composition of the invention, then the composition including all its components should also be searched and such search would discover prior art against Group I and thus it would not place an undue burden on Examiner to examine both the device and composition claims.

It is respectfully requested that the restriction is withdrawn, at least with regards to groups I and II and all claims 1-19 and newly submitted claims 29-46 be examined at the same time.

Election of Species Regarding Groups I-III

Examiner further requires election of species and argues that this application contains claims directed to more than one species of the generic inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

For example, the generic inventions encompass multiple species of pharmaceutical formulations; namely, a) foam, and b) film. These species possess different pharmaceutical properties. Thus, the species are independent or distinct because they exhibit different pharmaceutical characteristics. In view of the search burden that will be created by the divergent subject matter

encompassed by the claims, applicant is required to elect either a) foam, or b) film, for examination purposes.

Applicants elect, with traverse, to prosecute film species. However, Applicants submit that both the film and foam are attached to the device of the invention and if the device of the invention is found patentable, both the film and foam species will also be found to be patentable.

In addition, if applicant elects invention II, then applicant is further required to 1) elect a device wherein the foam or film is present as either a) coating, or b) incorporated into the device of claims 20 and 21 and also to 2) elect a single specific device from the below list for examination purpose; namely i) tampon, ii) tampon-like device, iii) ring, iv) sponge, v) pessary, vi) suppository, vii) pad, viii) strip, ix) cylinder, x) sphere, or xi) beads.

Applicants elect, with traverse, the species where the film is present as a coating on a tampon-like or tampon device. The traverse is based on the grounds that if the search is directed to the film or foam present as a coating on tampon-like device, such search would likely also discover the tampon or other devices being incorporated with film or foam.

Additional Election of Species Regarding Groups I-III

Examiner submits that the generic inventions encompass multiple species of polymers and that each specie exhibit different pharmaceutical properties and therefore represent a pharmaceutical agent. Thus, the species are independent or distinct because they exhibit different pharmaceutical properties. In view of the search burden that will be created by the divergent subject matter encompassed by the claims, is required to elect a single specific polymer for examination purposes e.g. hydropropyl methylcellulose, or gelatin, or alginic acid, or dimethyldiethoxysilane.

If applicant elects a composition comprising a combination of two or more polymer substrates (i.e. a mixture), then applicant is further required to specifically specify each constituent polymer substrate for examination purposes.

Applicants elect, with traverse, to prosecute polyethylene oxide as a polymer species. Traverse is on the grounds that polymers, albeit they might be chemically different, typically behave in the same way when they have the same function in the mucosal composition.

Election of Species Regarding Groups I-III

Further election is required on the basis that the generic inventions encompass multiple species of therapeutically effective agents. Each specie therefore represent a different pharmacologic agent. For example, the generic inventions include the following species: a) anti-osteoporotic, b) non-steroidal anti-inflammatory, c) calcium channel antagonists, d) local anesthetic, e) potassium channel

antagonists, f) β-adrenergic agonist, g) vasodilator, h) cyclooxygenase inhibitor, i) anti-fungal, j) antiviral, k) antimicrobial, l) antiparasitic, m) anti-epileptic, n) anti-migraine, o) anti-HIV, p) anti-neurodegenerative, q) anti-psychotic, r) chemotherapeutic or antineoplastic, s) analgesic agent, and t) biotechnology derived protein or peptide.

Examiner argues that the species are independent or distinct because they exhibit different pharmacologic activities have acquired a different status in the art. In view of search burden that will be created by the divergent subject matter encompassed by claims, applicant is required to elect a single therapeutically effective specie examination purposes e.g. anti-osteoporotic, or non-steroidal anti-inflammatory, or calcium channel antagonist, or s) opioid analgesic agent etc.

In addition, Applicant is further required to elect a single specific sub-specie the above listed species for examination purposes.

For example, if applicant elects a) anti-osteoporotic, then applicant is further required to elect a single specific anti-osteoporotic drug for examination purposes e.g. alendronate or if applicant elects b) nonsteroidal anti-inflammatory drug, then applicant is further required to elect a single specific nonsteroidal anti-inflammatory drug for examination purposes e.g. aspirin.

Applicants elect, with traverse, to prosecute non-steroidal anti-inflammatory agents with sub-species directed to ketorolac. The traverse is based on the ground that when formulated as a composition of this invention, the drugs in all groups have the same or similar release properties.

Election of Species Regarding Groups I-III

Still another election is required for the generic inventions that, according to the Examiner, encompass multiple species of topical drug delivery sites; namely, a) nasal, b) buccal, c) vaginal, d) labial, or e) scrotal epithelium. Each specie represents a distinct anatomical entity and exhibits different characteristics with respect to drug pharmacokinetics and pharmacodynamics as wells as having acquired a different status in the art. In view of the search burden that will be created the divergent subject matter encompassed by the claims, applicant is required to elect a single topical drug delivery site for examination purposes e.g. nasal, or buccal, or vaginal etc.

Applicants elect, with traverse, to prosecute claims directed to the vaginal device but respectfully point out that the epithelium tissue in all these organs or cavities is the same or similar and that the released drug formulated for a transmucosal delivery will be delivered through the mucosal tissue regardless where such mucosal tissue is located.

Election of Species Regarding Groups I-III

Examiner additionally requests election of species of sub-compositions comprising the following:

1) penetration enhancer, 2) sorption promoter, mucoadhesive agent, hydrophilic or hydrophobic release modifier, 5) or a mixture thereof, 6) additives or excipients.

Examiner argues that each specie composition exhibits different pharmaceutical properties. In view of the search burden that will be created by the divergent subject matter encompassed by the claims, applicant is required to elect a single composition wherein each constituent in the composition is specifically defined.

The above species are distinct as they exhibit different pharmaceutical and pharmacologic effects. The divergent subject matter, coupled with the fact that the species have acquired a different status in the art, creates a search burden on the examiner. In view of the undue search burden that will be created by the pharmaceutical agents and drug delivery sites encompassed by these claims, applicant is required elect one single cell specie or subcomposition for examination purposes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 20 are considered generic to the above listed species.

Applicants elect, with traverse, to prosecute species "penetration enhancer". The traverse is based on the grounds that the composition of the invention typically comprises several components in combination and to elect one element for search will also discover other components present in the composition.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which claims are readable upon the elected species. MPEP 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inventorship for the pending claims remains the same.

The examiner has required restriction between product process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 121. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP 821.04(b). Additionally, in order to retain the right rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.